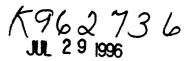
ATTACHMENT A



510(k) Summary:

1.) Submitter: Mill-Rose Laboratories, Inc.

7310 Corporate Blvd. Mentor, OH 44060 (216)255-7995

2). Contact Person: Alan C. Poje

3.) Summary Preparation Date:

July 12, 1996

4.) Classification Name: Bronchoscope and Accessory

5.) Common Name: Laryngoscopic Injection Needle

6.) Proprietary Name: Mill-Rose Laryngoscopic Injection Needle

7.) Substantially Equivalent Devices:

K914181: Wang/Mill-Rose Transbronchial Aspiration Needle

K820973: Endoscopic Injection Needle

8.) Description of Subject Device:

The device consists of an outer catheter and an inner catheter to which a needle is mounted. The inner catheter slides within the outer catheter such that the needle tip may advance a pre-determined distance past the end of the outer catheter and remains totally within the lumen catheter when the needle is fully retracted.

9.) Intended Use:

The device is intended to be used through a laryngoscope for the therapeutic injection the larynx for various laryngeal disorders such as paralysis, tissue deficiency, contact ulcers and spasmodic dysphonia.

10.) Technological Characteristics:

The subject device has the same technological characteristics as its predicate devices. It is composed of the same type of materials and is of a similar design.